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14. ABSTRACT

Trauma, hemorrhage and burns leads to hypovolemia and hypovolemic shock. Fluid therapy restores normalcy in physiological endpoints, such as cardiac output and blood pressure, but can result in secondary insults, such as excessive edema, if not titrated well. Fluid therapy is labor intensive and requires significant attention by caregivers, who can be overwhelmed in a mass casualty situation.

Closed loop fluid resuscitation systems hold great potential to optimize fluid therapy with fewer secondary insults, respond more quickly to changes in patient condition, automate caregiver tasks, reduce variability in care due to fatigue or inexperience and be a force multiplier in mass casualty situations. In this project we have iteratively developed a closed loop fluid delivery system (CLFDS) and conducted a human hemorrhage model clinical study. Clinical data indicates the CLFDS maintains target blood pressure with less fluid and extravascular fluid than the standard of care approach.

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1. Abstract

Trauma, hemorrhage and burns leads to hypovolemia and hypovolemic shock. Fluid therapy restores normalcy in physiological endpoints, such as cardiac output and blood pressure, but can result in secondary insults, such as excessive edema, if not titrated well. Fluid therapy is labor intensive and requires significant attention by caregivers, who can be overwhelmed in a mass casualty situation.

Closed loop fluid resuscitation systems hold great potential to optimize fluid therapy with fewer secondary insults, respond more quickly to changes in patient condition, automate caregiver tasks, reduce variability in care due to fatigue or inexperience and be a force multiplier in mass casualty situations. In this project we have iteratively developed a closed loop fluid delivery system (CLFDS) and conducted a human hemorrhage model clinical study. **Clinical data indicates the CLFDS maintains target blood pressure with less fluid and extravascular fluid than the standard of care approach.**

2. Scientific and Technical Objectives

This project's primary goal was to iteratively develop a Closed Loop Fluid Delivery System (CLFDS) prototype, collect clinical data in a human hemorrhage model, and plan next steps for safety and effectiveness testing for ultimate FDA approval.

Technical objectives included hardware, software and clinical study goals. The prototype hardware needed to be reduced in weight and cubic volume compared to prior efforts. Hardware development needed to focus on Commercial Off The Shelf (COTS) components where available. The software needed development for closed-loop or "cruise control" functionality, including engagement and disengagement rules. After hardware and software refinement, a clinical study (operational utility assessment) would be performed with investigational review board (IRB) approval to collect data in healthy patients undergoing a simulated trauma (blood donor) model. Broadly, the project phases were:

Phase 1: Select COTS hardware components

Phase 2: Develop Decision Support (DS) on COTS Platform

Phase 3: Develop Closed Loop (CL) on COTS Platform

Phase 4: Collect Clinical Data in a Human Hemorrhage Model

Phase 5: Develop Regulatory Plan for Closed Loop Pre-Market Approval

Operational Naval Concept

Due to the nature of naval operating missions, it is likely that evacuation of casualties may involve long transit times. It is during this time that the casualty is most vulnerable. The ability of an independent duty corpsman (IDC) to closely monitor a casualty is limited and made more so if attending to multiple casualties.

Combat injuries result in the loss of blood and other fluids that if untreated will lead to shock. The infusion of vital fluids is the primary treatment of hypovolemia. There exist, however, a tremendous range of how to perform this task. This is the "art" of fluid therapy, in which clinicians use intuition, experience, injury type and severity and other vital information to increase or decrease the infusion of vital fluids to restore vascular volume. Still, even in top tertiary care centers, direct endpoints are infrequently and non-systematically used to guide volume resuscitation. Fluid resuscitation in the combat casualty is further challenged by limited care-giver experience, lack of vital information, injury severity and other logistic constraints. This is overwhelming. More precise fluid management can be realized so that the clinical sequelae of hypovolemia and hypervolemia from under and over resuscitation will be reduced. Serious injuries need a solution that is resolute and attainable to increase survivability of our wounded sailors and marines.

We suggest that a fluid delivery system implementing closed loop prescription-based fluid therapy will provide a practical, reliable, quickly responsive, and consistent solution to such injuries. This closed loop fluid delivery system (CLFDS) will integrate a vital signs monitor (VSM) and high speed infusion pump (Pump) to respond quickly to drops in blood pressure by appropriately fluid therapy (bolus size or flow rate), resulting in improved fluid therapy care for military casualty evacuations.

3. Approach

This project benefitted from previous development performed by ONR Grant N000-1406-0300, Closed Loop Resuscitation of Hemorrhagic Shock, Dr. George Kramer, PI, University of Texas Medical Branch (UTMB). Dr. Kramer's work resulted in a Decision Support prototype system.

Our hardware development approach was iterative development of the prototype system using COTS components where possible. Many technical design constraints were considered when evaluating dozens of candidate components to make the system lighter, smaller, and more robust.

The clinical study approach was a human hemorrhage (blood donor) model intended to simulate a trauma injury. General anesthesia was used to provide a drop in blood pressure and to blunt the compensatory response to hemorrhage, which exaggerates the hemodynamic response to even mild hemorrhage. The initial proposal called for three arms of fluid therapy after blood withdrawal: 1) Standard Of Care (SOC) albumin therapy, 2) CLFDS led albumin therapy and 3) CLFDS led whole blood therapy. Subjects were randomized to arm. During the project the whole blood arm was halted due to the slow rate of studies and time constraints; we choose to focus on the main comparison between SOC and CLFDS albumin therapies.

The regulatory plan approach involved getting a 510(k) on the decision support device as well as using the clinical study data to develop a more formal clinical trial plan for the closed loop system. Our initial plan was to get an FDA IDE Agreement Meeting commitment in order to reach an agreement with FDA on the clinical trial size. During the course of this development, we have given more weight to need to demonstrate sufficient safety for the infusion pump system (hardware, software, human factors) as an earlier regulatory goal than the definitive clinical trial for the closed loop system. Based on FDA's new guidance for Pre-Submissions, we submitted a Pre-Submission for a 510(k) requesting FDA's feedback on our safety assurance case.

4. Concise Accomplishments

Start through May 2012

This award began 5 March 2012. From then until 31 May 2012 we performed a hazard analysis risk assessment, identifying several risks that need mitigating by design or other risk controls. The risk assessment report will guide software and hardware design decisions during development and testing. We also screened many rugged COTS tablets for us as the main controlling computer of the CLFDS. We acquired and tested a few tablets in-house and provided a detailed comparison report with ranked candidates.

June 2012 – May 2013
From 1 June 2012 until 31 May 2013, we selected the ideal hardware platform that meets all the technical requirements and was most favored by end user down selection, we completed the pump data acquisition and control capability, we completed the pump case modification, we tested performance of the decision support system compared to the predicate device and, having matched performance, reached Technology Readiness Level 6, we completed a night vision goggle assessment, and we completed the CLFDS prototype.

June 2013 – End
From 1 June 2013 until the end of the project, we conducted the clinical study. The comparison between the standard of care (1:1 replacement) and CLFDS-led albumin fluid therapies showed **the closed loop fluid delivery system maintained blood pressure with reduced fluid needs in a human hemorrhage model. This initial study also suggests less extravascular volume in the CLFDS-led therapy set.** These results point toward a tangible method of improving treatment of hypovolemic shock due to trauma and other common injuries sustained by warfighters.

5. Expanded Accomplishments

Phase 1: Select COTS hardware components

The CLFDS comprises three main components: a vital signs monitor, a high speed infusion pump and a tablet computer. The tablet computer houses the control algorithms, contains the main Graphical User Interface (GUI), asks the user for physiological information, such as patient injury type and alertness, and shows fluid data.

Although the number of tablets and handheld computers have exploded in recent years, we focused on tablets that were "rugged" (met MIL-STD 810G) to be suitable for the en route care casualty evacuation system.

We successfully integrated the lightweight, Athena Wireless Vital Signs Monitor (WVSM) into the system.

Several reliability and safety aspects, particularly at a software driver level, prompted investigation of a real time operating system (RTOS). We installed the QNX RTOS on a few tablets. We investigated the ability to install QNX, QNX's communication with external devices, battery life and more aspects. We found that QNX has mixed results of performance, capability and flexibility when installed on different COTS tablet computers.

Although an RTOS is not a strict requirement to ensure safety and reliability for life supporting or life sustaining medical software, it is much easier to justify low probability of failures for many risks when an RTOS is used. We continue to investigate software and hardware solutions that sufficiently mitigate known hazards for the CLFDS.

We compared several aspects of seven rugged COTS tablets for CLFDS use, including ruggedness, battery life, input/output connectivity options, weight and screen size. **We**

integrated the Panasonic Toughbook H2 model, because QNX could operate with the required I/O communication methods, it was one of very few tablets that has undergone Joint JECETS airworthiness testing (and only one that has passed as a medical device platform) and it presented a nice balance of many tablet characteristics.

For the infusion pump, we utilized a COTS ZOLL Power Infuser, a high speed infusion pump specifically designed for rapid infusion of fluids for trauma patients in a transport environment.

In order to operate the infusion pump remotely, we needed a data acquisition interface between the main tablet and the pump.

We determined that successful data acquisition and several new safety and reliability features could be realized if we included a microcontroller in the infusion pump. We designed the microcontroller and designed a case expansion to house the microcontroller within the pump. Production of the microcontroller required a small design change to the microcontroller schematic. After testing microcontroller units as produced, we then assembled the microcontrollers in the pump.

The microcontroller interface to the pump enabled external data acquisition and control of the pump and opened up several new features:

- Pump battery meter
- Ability to hot swap pumps
- Ability to continue therapy if communication does down between the user interface tablet and the pump
- Ability to auto-resume therapy after the user clears an alarm condition
- Ability to calibrate pump motor to each fluid type

These features provide more safety for the end patient, increase system reliability and increases convenience for the user.

In addition to the individual sub-system improvements, total hardware system miniaturization resulted in a 40% reduction in weight and smaller system footprint.

Figures 1 and 2 below shows the hardware platform before and after new hardware sub-system integration.

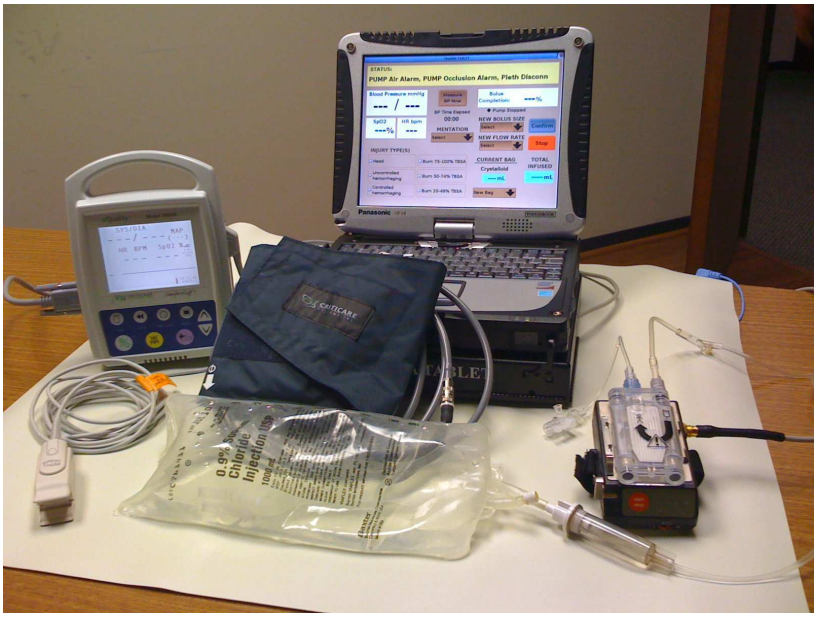

Figure 1 - FY2010 Prototype system

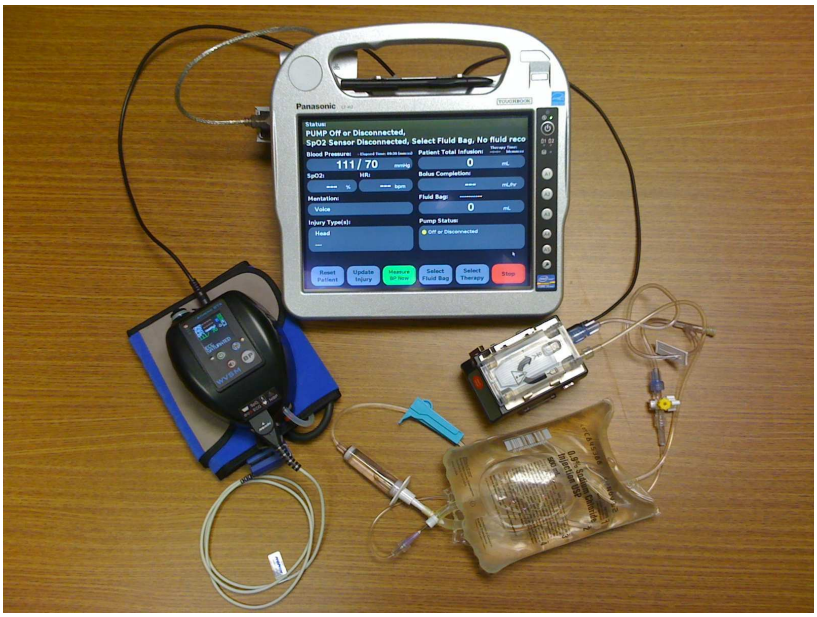

Figure 2 - FY2013 System, a 40% reduction in weight and smaller footprint

Phase 2: Develop Decision Support (DS) on COTS Platform

The Graphical User Interface (GUI) shows VSM data, allows the user to select from several injury types (head, uncontrolled hemorrhage, controlled hemorrhage, and three total body surface area (TBSA) categories of severe burns), mentation states (alert, voice responsive, pain responsive, and unresponsive). The GUI also allows the user to choose from several bolus sizes and flow rates. The GUI includes a pump indicator (% bolus completion, or current flow rate being delivered), a total infused volume indicator, a current bag volume calculator, and a status bar for alert and non-alert messages.

We made several improvements to the device software, including simplifying the user interface and refining much of the application handling. Application handling includes issues such as how the software keeps patient data if the device loses power, operation of the pump and software if there is a disconnect between the pump and user interface tablet, and how the software should respond if the user turns off the pump versus pauses the pump during a fluid bag change. These examples are just a few of the many scenarios and use issues involved with the CFLDS.

We also designed the software architecture to enable inter-operability with multiple vital signs monitors.

We then tested the performance of the decision support system and compared the results to the predicate device. We found that bolus volumes and flow rates were delivered with the same accuracy as the predicate device.

Crystalloid Flow Rate Test Data Results

Fluid Type: Lactated Ringers
Pump Cartridge: Crystalloid/Colloid
Catheter Size: 18 gauge

Test	Flow Rate (mL/hr)	Test Time (minutes)	Target (mL)	Measured (mL)	Deviation (mL)	Deviation (%)	Pass/Fail (+/-15%)
1	1000	6	100	107	7	7	Pass
2	600	6	60	64	2	6.67	Pass
3	500	6	50	52	2	4	Pass
4	300	6	30	34	4	13.3	Pass
5	200	6	20	23	3	15	Pass

Crystalloid Bolus Test Data Results

Fluid Type: Lactated Ringers
Pump Cartridge: Crystalloid/Colloid
Catheter Size: 18 gauge

Test	Bolus Size (mL)	Target (mL)	Measured (mL)	Deviation (mL)	Deviation (%)	Pass/Fail (+/-15%)
1	500	500	520	20	4	Pass
2	250	250	256	6	2.4	Pass
3	100	100	103	3	3	Pass

Colloid Bolus Test Data Results

Fluid Type: Hextend
Pump Cartridge: Blood
Catheter Size: 16 gauge

Test	Bolus Size (mL)	Target (mL)	Measured (mL)	Deviation (mL)	Deviation (%)	Pass/Fail (+/-15%)
1	500	500	485	-15	3	Pass
2	250	250	245	-5	2	Pass
3	100	100	98	-2	2	Pass

Whole Blood Bolus Test Data Results

Fluid Type: Whole Blood, blood sample used was pig blood
Pump Cartridge: Blood
Catheter Size: 16 gauge

Test	Bolus Size (mL)	Target (mL)	Measured (mL)	Deviation (mL)	Deviation (%)	Pass/Fail (+/-15%)
1	100	100	114	14	14	Pass
2	100	100	113	13	13	Pass
3	100	100	110	10	10	Pass
4	250	250	270	20	8	Pass
5	500	500	535	35	7	Pass

Whole Blood Flow Rate Test Data Results

Fluid Type: Whole Blood, blood sample used was pig blood
Pump Cartridge: Blood
Catheter Size: 16 gauge

Test	Flow Rate (mL/hr)	Test Time (minutes)	Target (mL)	Measured (mL)	Deviation (mL)	Deviation (%)	Pass/Fail (+/-15%)
1	1000	6	100	108	8	8	Pass
2	600	6	60	63	3	5	Pass
3	500	6	50	49	-1	-2	Pass
4	300	6	30	32	2	6	Pass
5	200	6	20	21	1	5	Pass

The bench testing results show that the Trauma Tablet System passes all accuracy tests when used with the manufacturer's specified configuration. **The data shows that the Trauma Tablet System operationally performs as well as the predicate device in delivering fluid therapy.**

The performance results mean the system has reached Technology Readiness Level 6.

Phase 3: Develop Closed Loop (CL) on COTS Platform

We then developed Closed Loop mode. **We determined and defined several Engage and Disengage behaviors in order to safely start and exit from Closed Loop mode.** For example, we required that all the component systems had to be communicating without errors before closed loop mode could be engaged. Additionally, an alarm condition would automatically disengage closed loop mode. An alarm condition, such as air in the pump line, requires attention by the user and rightly should stop the infusion to the patient. Only after the user has resolved the alarm condition can the device be placed back in closed loop mode.

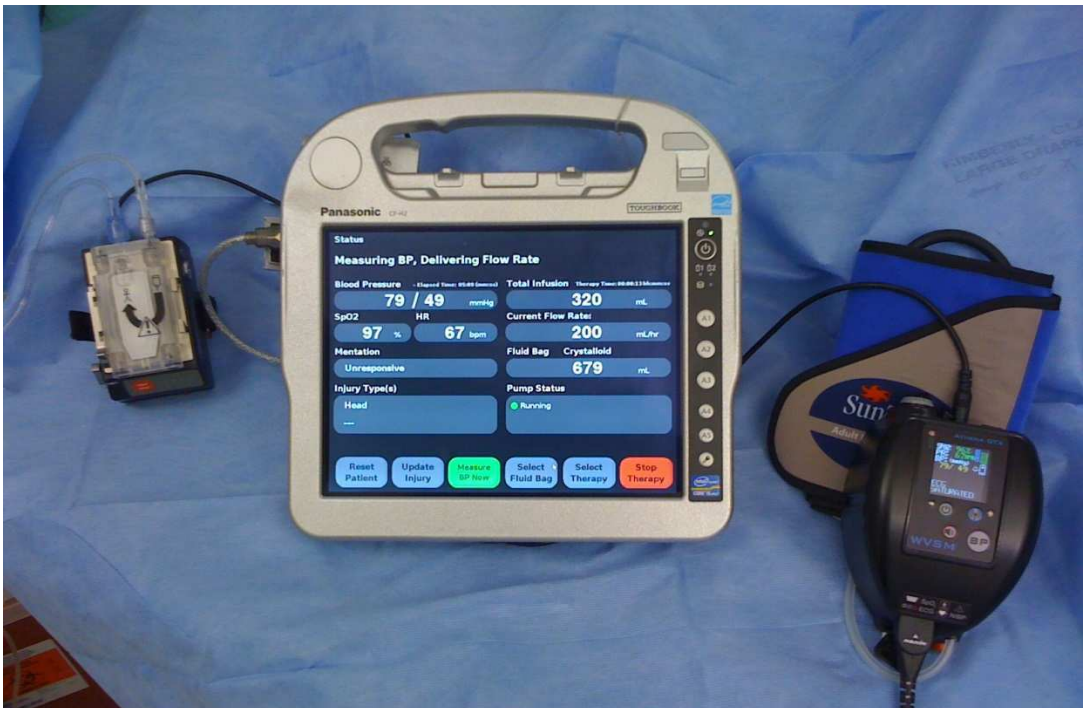

Figure 3 - System Configuration

Phase 4: Collect Clinical Data in a Human Hemorrhage Model

We evaluated the effectiveness of Closed Loop Fluid Delivery System [CLFDS] for albumin to standard of care infusion of albumin resuscitation during mild hemorrhage in healthy volunteers. Studies were performed at the Clinical Research Center (CRC) at UTMB after IRB and CRC approval. The computerized algorithm provided automated specific fluid infusion rates/volume based on blood pressure. The algorithm was also adaptable, meaning that fluid volumes were adjusted based on baseline or starting blood pressure. The main input variable, mean arterial blood pressure, was measured every 2-5 min. The modified ZOLL Power Infuser administered albumin in a specific high flow rate, which equated to volume. The standard of care replacement fluid resuscitation regimen for albumin in treatment of hemorrhage was 1:1 or 10 mL/kg.

Experimental Protocol (Figure 4): Healthy volunteers, n=4 (ASA I) were pre-screened and underwent 3 different fluid resuscitation regimens or Arms, separated by at least 4 weeks:

Arm 1: Standard of Care = fixed 10 mL/kg fluid bolus over 20 min (SOC)

Arm 2: CLFDS = Albumin infused as needed per MAP

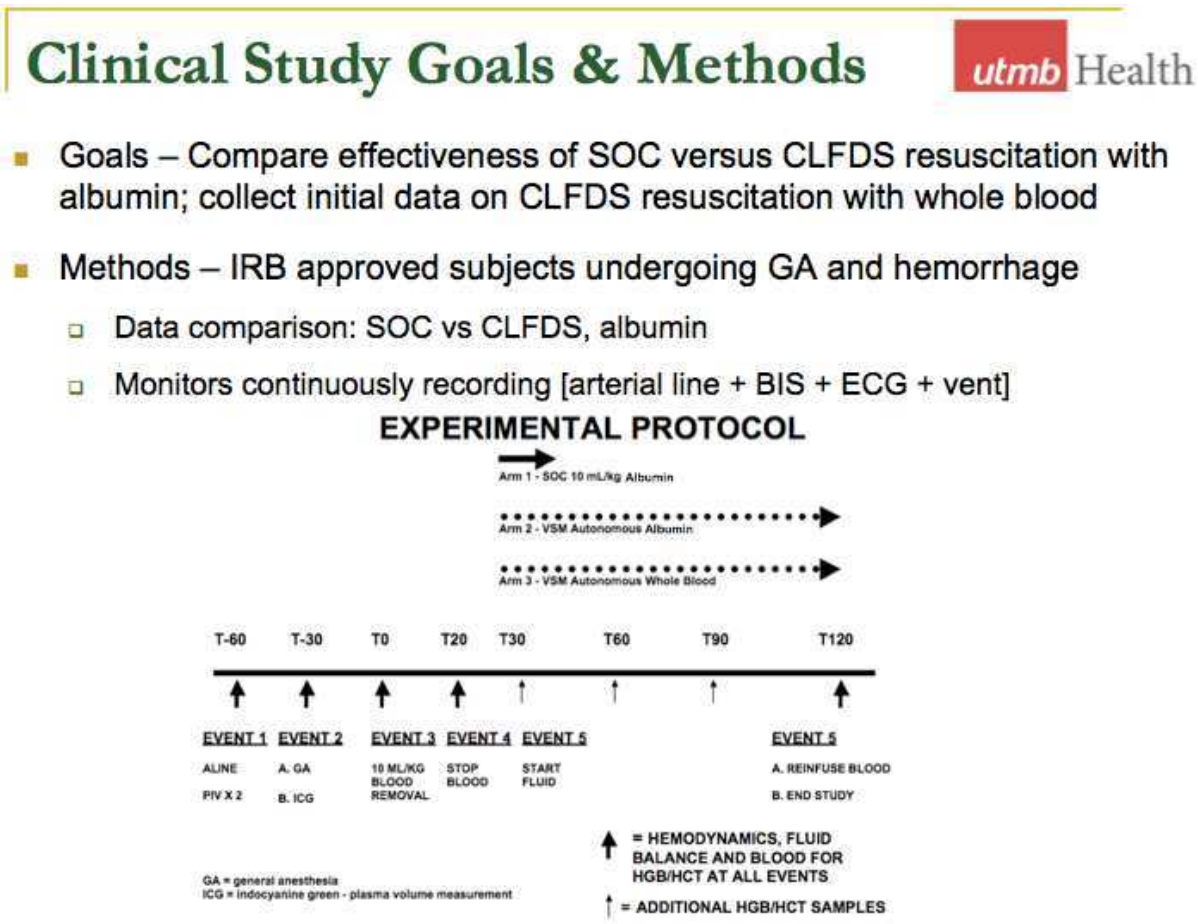

Figure 4 - Experimental protocol

Clinical Study Results

Data [Mean ± SEM] are summarized for 4 subjects receiving albumin resuscitation [CLFDS vs SOC]. Also, pilot data is presented for the whole blood arm. Other funding may be used to examine the effect of whole blood and enroll additional subject[s] to address the scientific hypothesis that the albumin resuscitation using CLFDS can better maintain blood pressure with less fluid.

<u>Mean Arterial Pressure [target]</u>: General anesthesia reduced blood pressure by 25%. **Target blood pressure was better maintained in the CLFDS group as represented by lack of reduction in BP after start of resuscitation.** The SOC albumin group was associated with a leveling in blood pressure or limited response even after a larger rate and dose of albumin was administered.

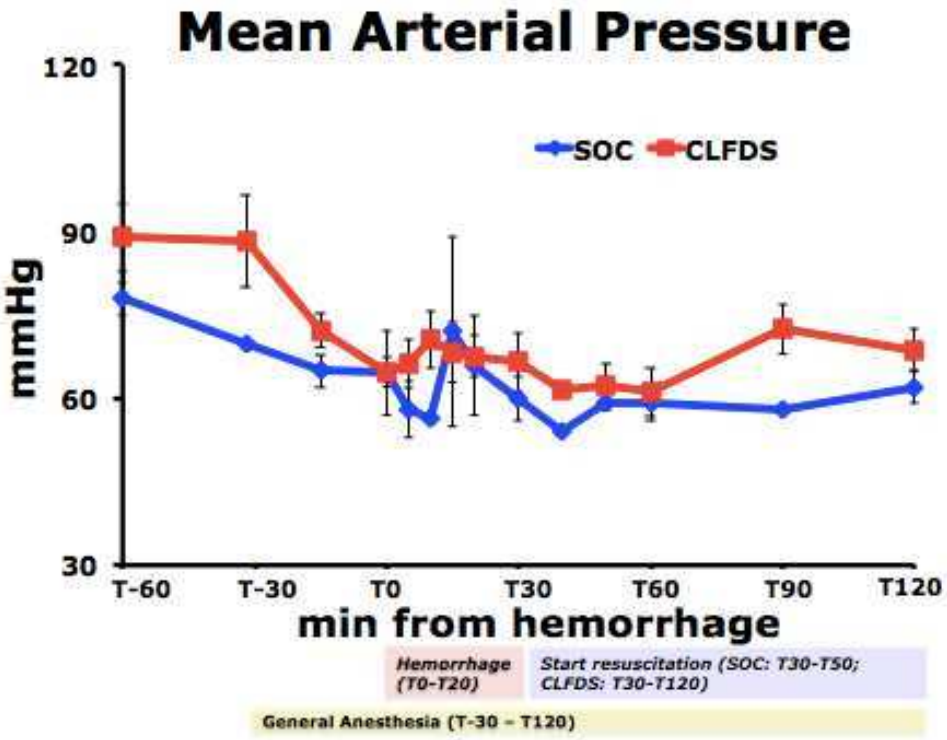

Figure 5 - Mean arterial pressure

Hemodynamics: There was a mild increase in heart rate during hemorrhage, which returned towards baseline after resuscitation with CLFDS – although this effect was not likely statistically significant. Hemorrhage had little effect on cardiac output. The preserved cardiac output could be due to increased heart rate response. On the other hand, both fluid resuscitation groups [CLFDS and SOC] resulted in an increase in cardiac output. Since the increase in cardiac output was not associated with a concomitant increase in MAP, a fall in systemic vascular resistance occurred during resuscitation. Stroke volume, which represents cardiac output divided by heart rate, was associated with a small decrease during the hemorrhage but thereafter increased as the result of the resuscitation.

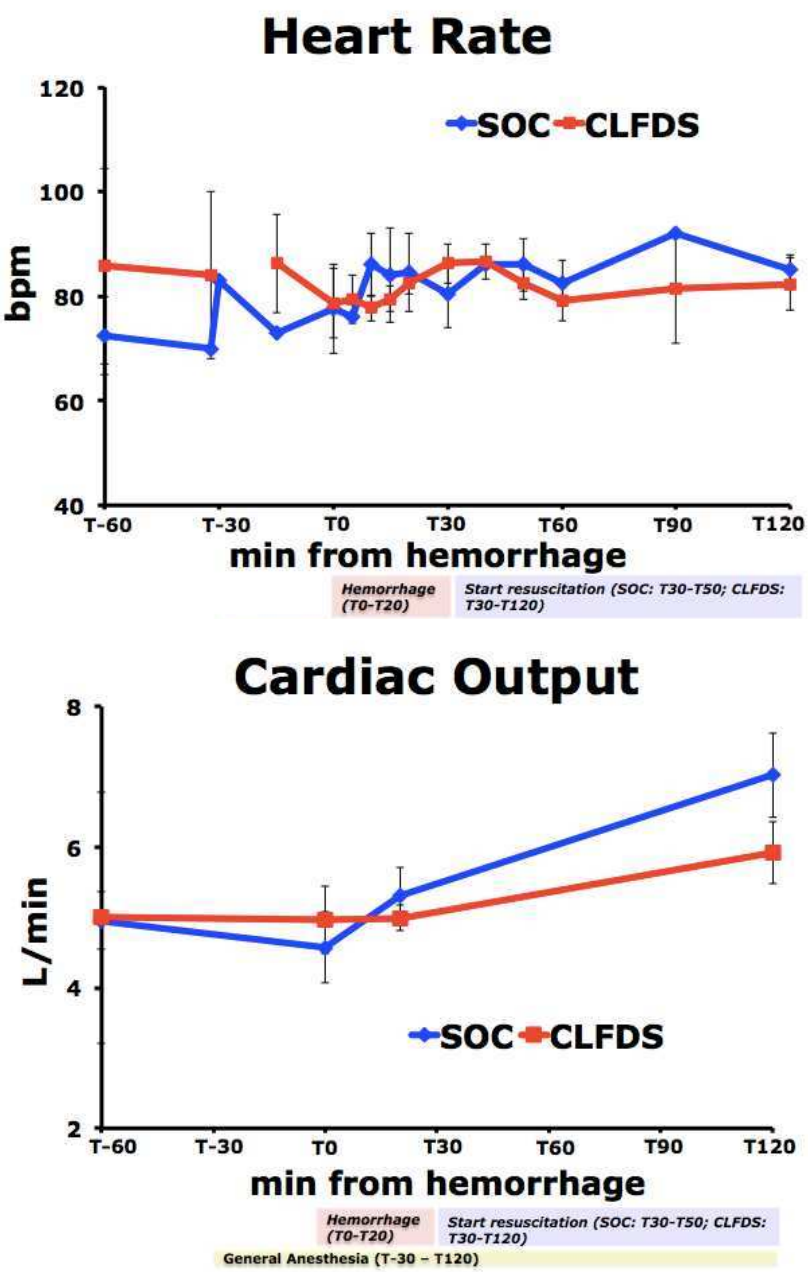

Figure 6 - Heart rate and cardiac output

Volumetric data: We measured total fluid in, urinary output, plasma volume, and extravascular volume. Total fluid requirements: The standard of care group received a fixed fluid dose of albumin or 10 mL/kg over 20 min. Albumin, a colloid, is theoretically maintained in the vascular compartment and volume deficits are replaced 1:1. Thus, since there was a 10 mL/kg hemorrhage, the amount of albumin replaced was 10 mL/kg. The CLFDS used varying bolus volumes based on blood pressure to administer albumin. Thus, the amount of albumin was directly related to the response of blood pressure. **The CLFDS group received 50% less fluid than the SOC group.**

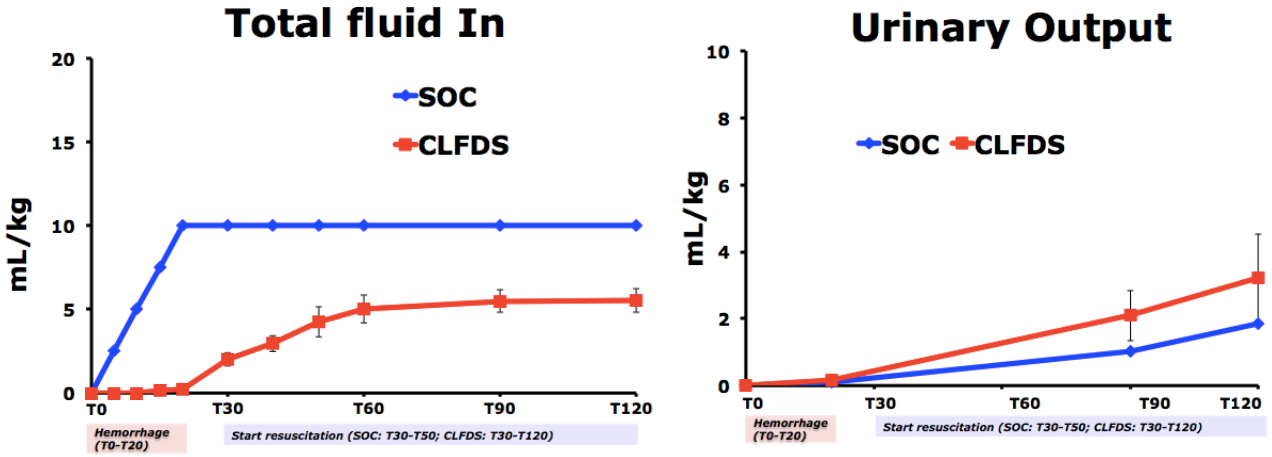

Figure 7 - Total fluid in and urinary output

Urinary output was measured by bladder ultrasound. A definitive urine volume was recorded at study end. Despite an overall reduction in fluid administration in the CLFDS group, urinary output was not associated with a reduction. Urinary output is often used by clinicians to assess overall perfusion and regional blood flow e.g., kidneys. Urinary output can be modulated by total body water, blood flow, pressure and other hormonal and physiologic factors. The similar urinary output between CLFDS and SOC is reassuring that perfusion is likely competent.

Plasma volume expansion was determined from measured hematocrit and the accounted red cell mass removal. Extravascular volume expansion represented the amount of volume administered minus the amount of plasma volume expansion and urinary output. Therefore, extravascular volume expansion represented fluid retained in the body that is not circulating e.g., interstitial fluid or edema.

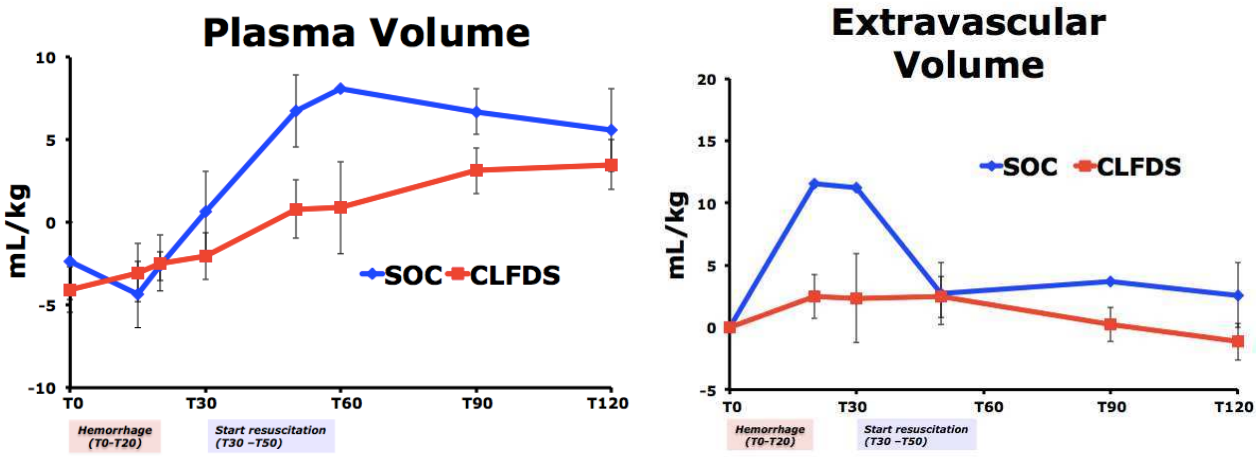

Figure 8 - Plasma volume and extravascular volume

The SOC group was associated with an initial larger increase in plasma volume but by end of study, both groups' plasma volume expansions were similar. Thus, suggesting a mild increase in overall fluid volume. The extra vascular volume was larger in the SOC, which will likely be significantly larger during the initial resuscitation.

Overall, CLFDS maintained target blood pressure with less fluid and extravascular fluid than standard of care. These results point toward a tangible method of improving treatment of hypovolemic shock due to trauma and other common injuries sustained by warfighters, which has clinical and logistic appeal.

Phase 5: Develop Regulatory Plan for Closed Loop Pre-Market Approval

We created a Pre-Submission for a 510(k), following FDA's new Guidance for early interactions. FDA has highlighted several concerns with infusions pumps on the market and began requiring a safety assurance case for infusion pump 510(k)s in 2010. Our Pre-Submission includes the core components of the 510(k) application. In the Pre-Submission we ask FDA to provide specific feedback on our safety case. We are gathering feedback from ONR on the safety case prior to sending it to FDA for review.

The safety case we have developed lays out the core argument for why our algorithmic Goal Directed Fluid Therapy (GDFT)-based infusion pump system is safe for clinical use. It will serve as the bedrock for future Closed Loop Fluid System Pre-Market Approval application(s) to FDA.

6. Major Issues

Clinical study testing revealed a couple significant technical obstacles of the current approach. The COTS infusion pump used in this study allows free flow when the fluid bag is elevated above the patient level. This aspect can be useful in a transfer situation, such as between pre-hospital and emergency department transfer, where an EMT disconnects the pump from the

cartridge (in line with the patient) and hangs the fluid bag, thus allowing a minimum flow rate while taking the pump equipment back to the ambulance. However, this same aspect can frustrate precision efforts; if the bag is elevated a few feet above the patient, fluid rate inaccuracies can reach or exceed 50% of the intended flow rate.

Clinical study testing also revealed that the COTS infusion pump's occlusion alarm was insensitive for the user's needs. In one study, the user forgot to unclamp a pinch clip on the patient side of the IV tube set going to the patient. The pump operated for approximately 90-120 seconds before the anesthesiologist noticed no fluid going to the patient. The pump alarm then sounded. The calculation of total fluid given to the patient was frustrated by this situation where the pump is running although no fluid is actually being delivered to the patient.

We conceptualized two ways to solve both technical obstacles. First, a fluid monitor could be added to the system, which would calculate the amount of fluid leaving the bag (which typically gets infused into the patient) based on the bag weight. This solution, however, would only tell us whether there was free flow and would not prevent the free flow. Second, a different infusion pump or pressure infuser could be used to give the fluid therapy. Such a design would be able to prevent free flow when bags are hung. Since IV bags are typically hung for the vast majority of fluid therapy, it is preferential to design the system that takes clinical user habits into account.

7. Technology Transfer

Arcos has interacted with the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research and Technology Applications (ORTA), also known as the Technology Transfer Office, on expanding licensing for a similar fluid resuscitation device, the Burn Resuscitation Decision Support System (BRDSS), trade name Burn Navigator™. Arcos has indirectly licensed the BRDSS patent family for commercialization.

Using a similar development path, Arcos was awarded a cooperative agreement for development of the BRDSS, to include obtaining 510(k) clearance on the technology. Arcos received the award in June 2011 and obtained FDA 510(k) clearance in April 2013, 22 months later. Arcos is now actively commercializing the BRDSS technology to DOD and civilian customer.

The CLFDS technology is similar to the BRDSS in that they both seek to advance the state of the art of fluid resuscitation for certain critical care patients. UTMB has certain invention disclosures related to earlier ONR funded activities on closed loop fluid technologies, but no new patents are available for licensing at this time.

Arcos continues to actively commercialize DOD funded technology and to seek out further development and licensing opportunities with ONR funded research and development.

8. Foreign Collaborations and Supported Foreign Nationals

None.

9. Productivity

Invited Conference Presentations:

- Kinsky M, Salter M, Mileski W, Whitehead W, Enkhbaatar P, Kramer G, “Automated Critical Care Fluids”. Smart Monitoring; 2013 Aug 10-11, Fort Lauderdale, FL.

Press:

- H Rice, “Emergency room in backpack being developed for battlefield.” A1, Houston Chronicle, June 17, 2013.
- J Reynolds, “Critical care in a backpack.” A1, Galveston Daily News, June 25, 2013.

10. Award Participants

The following people received salary support from this ONR award:
Christopher Meador, Arcos
Dave Inlow, Optimation
Elvis Zapalac, Optimation
Michael Kinsky, UTMB
Sheryl Henkel, UTMB
Michael Salter, UTMB